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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,891	01/02/2002	Jeffrey T. Borenstein	62030(51588)	8813
21874	7590	09/26/2006	EXAMINER	
EDWARDS & ANGELL, LLP P.O. BOX 55874 BOSTON, MA 02205			NAFF, DAVID M	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/038,891	<b>Applicant(s)</b> BORENSTEIN ET AL	
	<b>Examiner</b> David M. Naff	<b>Art Unit</b> 1651	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1 and 5-58 is/are pending in the application.  
     4a) Of the above claim(s) 27 and 33-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 5-26, 28-32 and 38-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for  
5 continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/5/06 has been entered.

Claims in the application are 1 and 5-58

10 An amendment of 7/5/06 amended claims 1, 25, 28 and 32, canceled claim 2, and added new claims 39-58.

Claims 27 and 33-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely  
15 traversed the restriction (election) requirement in the reply filed on 7/21/04.

Claims examined on the merits are 1, 5-26, 28-32 and 38-58.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

20 ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C.

112:

25 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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Claims 1, 5-26, 28-32 and 38-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey  
5 to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Adequate support is not found in the specification for (b) as amended of claim 1 and for (C) of claims 28 and 32. The portions of the specification cited for support do not describe a procedure of the  
10 breadth and scope in regard to photoresist processing technique in (b) of claim 1 and in claim 40, semiconductor manufacturing process in (C) of claim 28, molded by optically creating a microfluidic pattern on a substrate in (C) of claim 32, and thick resist process technique in claim 50.

15 The specification fails to support a thickness of 10 to 500 microns thick in (a) and 2 to 50 microns in height and width in (iii) of claim 25 and in (b) of claim 58. The specification discloses the 10 to 500 microns as being used in the prior art rather than in the invention. A range of 2 to 50 microns for the channels is not  
20 apparent in the specification.

Support for new claims 39-58 is not readily apparent in the specification. The page and line where each claim is supported should be pointed out. Claim 58 is supported except as noted above.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C.

112:

5       The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10       Claims 1, 5-24, 28-32 and 38-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15       The last three lines of claim 1 and (C) of claims 28 and 32 are unclear as to the procedure carried out by not setting forth a complete for producing the first layer. The procedures do not require producing microchannels as required in (a) and (i) of the claims. Additionally, it would be uncertain as to process steps performed by the photoresist processing technique in (b) of claim 1, semiconductor manufacturing process in (C) of claim 28, molded by optically creating a microfluidic pattern on a substrate in (C) of claim 32, and thick  
20       resist processing technique of claim 50. The steps should be set forth required to carry out photoresist processing technique, semiconductor manufacturing process, molded by optically creating a microfluidic pattern on a substrate, and thick resist processing technique.

25       Claims 45 and 46 do not have clear antecedent basis in claim 1.

      Claim 49 does not have clear antecedent basis for "the lumens", which are not required in claim 25.

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Claim 54 is confusing as to the difference in adding, loading and seeding.

In claim 56, the abbreviation should be preceded by the full name to be clear.

5        Claim 58 is unclear as to the part of the device that has a thickness of about 10 to 500 microns in the penultimate line.

***Claim Rejections - 35 USC § 103***

10        Claims 25, 26, 49 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiss et al (6,143,293) in view of Vacanti et al (6,139,574) and Mastrangelo et al (6,136,212), and if necessary in further view of Cima et al (5,518,680) or Marra et al (6,165,486).

15        The claims are drawn to method of making a multilayer device and to a multilayer device. In the method, a first polymer scaffold layer is formed for attachment and culturing of cells and containing a pattern of microchannels 2 to 50 microns in height and width and being 10 to 500 microns thick, a second layer of a polymer scaffold for attachment and culturing of cells is obtained, and the first and second layers being fastened or joined together.

20        Weiss et al disclose a scaffold containing multiple layers fastened together. Weiss et al further disclose the scaffold containing microchannels to help support angiogenesis and to support cell growth (col 4, lines 52-56).

25        Vacanti et al disclose a scaffold for tissue regeneration containing interconnected pores.

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Mastrangelo et al disclose producing microfluidic devices containing micromachined microchannels.

It would have been obvious to provide layers of the scaffold of Weiss et al with interconnecting microchannels for cell growth as suggested by Weiss et al disclosing microchannels to support angiogenesis and cell growth and Vacanti et al disclosing a scaffold having interconnected pores for cell growth and Mastrangelo et al disclosing producing microfluidic devices having microchannels. Microchannels in the scaffold of Weiss et al would have been expected to be advantageous for the same reason that Weiss et al found microchannels to be advantageous, i. e. to support angiogenesis and to support cell growth. Providing microchannels 2 to 50 microns in width and height as in claims 25 and 58 would have been a matter of obvious choice depending on the size of cells desired to enter the channels, and would have been a matter of individual preference well within the skill of the art. A thickness of about 10-500 microns in claims 25 and 58 would have been a matter of individual preference within the skill of the art.

#### ***Response to Arguments***

Applicant's arguments filed 7/5/06 have been fully considered but they are not persuasive.

Applicants point out what each reference discloses, and how the reference differs from the invention. However, the references are applied in combination, and the invention becomes obvious when the references are considered together as a whole rather than each alone.

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Contrary to applicants' assertion, Weiss et al is not related to only to macroscale features. Weiss et al disclose forming microchannels to help support angiogenesis and to support cell growth (col 4, lines 52-56). It would have been obvious to form these  
5 microchannels by micromachining as suggested by Mastrangelo et al.

Applicants urge that there is no suggestion in Mastrangelo et al to form a 3D structure, and the polymers are etched, not molded. However, the present claims do not require molding and do not exclude etching. A 3D structure is suggested by Weiss et al.  
10 Microfabrication is clearly suggested by Weiss et al and Mastrangelo et al by disclosing microchannels and devices having micromachined microchannels. It would have been clearly obvious to provide the scaffold of Weiss et al with microchannels for their function as suggested by Weiss et al and Mastrangelo et al.

15 It is granted as urged by applicants that Vacanti et al is not micromachining. However, Vacanti et al is combined with the Weiss et al and Mastrangelo et al references, which suggest microchannels and micromachining.

Applicants refer to paragraph 196 of the specification as  
20 demonstrating a resolution of 2  $\mu$ m. However, the present claims do not require a polymer scaffold produced as in paragraph 196 of the specification. As to microchannels of about 2 to 50 microns in width and height, the scaffold of Weiss et al can contain pores of 200-400 microns (col 2, line 60) and the matrix of Vacanti et al can have  
25 pores of 5-80 microns (col 15, line 39) or 10-20 microns (col 12, line



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61) and channels of 60-300 microns (col 17, line 18). Thus, it would have been apparent to the ordinary skilled artisan that channel size can vary, and will depend on preferred size desired for a particular use or cell size to enter the scaffold. The specification discloses  
5 that channel size can be 5-500 microns (paragraph 78), and no critically has been established in using a channel size of 2-50 microns. The specification discloses that this channel size is merely a size for endothelial cells to enter. Weiss et al disclose that current approaches use a type of scaffold material to promote one type  
10 cell growth. When the cell type is endothelial cells, it would have been obvious to select a channel size for these cells instead of for bone cells as in Weiss et al. Selecting a particular channel size merely because the size allows a certain cell to enter would have been obvious and within the ordinary skill of the art. A thickness of 10  
15 to 500 microns would have been a matter of obvious choice in view of the disclosures of the references.

The request for an interview is noted. However, an interview is not deemed appropriate at this time. If an interview is still desired after receiving this office action, the examiner be contacted and an  
20 interview requested.

#### **Conclusion**

Claims 1, 5-24, 28-32, 38-48 and 50-57 are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff

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whose telephone number is 571-272-0920. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David M. Naff  
Primary Examiner  
Art Unit 1651

DMN  
9/18/06